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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,072	12/04/2003	Ron Heil	GUID.626PA	7645

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EXAMINER	
SMITH, STEPHANIE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

C.

Office Action Summary	Application No.	Applicant(s)	
	10/728,072	HEIL ET AL.	
	Examiner	Art Unit	
	Stephanie Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-5, 9, 16-19, 21-22, 31-34, 46-49, 53-56, 58, and 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Kieval (U.S. 6178349). Referring to claims 1-2, 21, 33, 48, and 55, Kieval teaches an implantable medical device for treatment of cardiovascular disorders that includes an implantable pulse generator, an electrode and a reservoir (see column 3, lines 57-61). The electrode is connected to the pulse generator by a lead, and a reservoir to delivery an alkaloid to the tissue is coupled to the lead (see figures 1 and 2, elements 90, 96, 98, 92, 94, 116, 114, 120, 122, 124, and column 4, lines 49-67, and column 5, lines 28-58). Kieval further teaches that the electrode stimulates a nerve that affects cardiovascular activity (see column 3, lines 11-16). Regarding claim 4, Kieval teaches that the electrode may include a plurality of individual electrodes (see column 5, lines 42-43) and that a steroid-eluting body may be associated with the electrode (see column 5, lines 43-45) and that the base and the container may be integrally formed (see column 6, lines 27-28). With reference to claims 5, 19, 22, 34, 49, 56, 58, Kieval discloses delivery of a nerve stimulating drug regulated by an apparatus that is an electromagnetic-based device and includes magnets electrically connected to the pulse generator by a lead (see column 7,

lines 3-24 and lines 49-53). Regarding claim 9, Kieval teaches that the base of the electrode assumes a cuff configuration and the reservoir is associated with the configuration (see figure 2 and column 5, lines 48-50). With reference to claims 16, 31, 46, 53, and 65, Kieval discloses that the reservoir elutes veratrum alkaloid (see column 6, lines 3-5). Referring to claims 17, 32, 47, 54, and 66, the nerve stimulation drug simulates a pressure rise in the carotid sinus bodies (see column 6, lines 46-48). With regards to claim 18, Kieval discloses the system described above, and further teaches that the can is configured to provide phoresis delivery because the pulse generator can control the regulating apparatus (see column 7, lines 3-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 6-8, 10-15, 25-26, 29-30, 35-42, 44-45, 50-52, 57, and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval in view of Shapland et al (U.S. 5628730). Kieval discloses the system and method described above, but does not disclose a transducer that provides sonophoresis; providing therapeutic treatment localized to a dissection path; that the pharmacological agent is provided at a plurality of locations on the lead body; that the pharmacological agent is impregnated into a membrane provided on the lead; that the lead comprises a polymeric structure, a porous region, or a doped polymer matrix; that the pharmacological agent is disposed on a coating on the lead; that the pharmacological agent is an analgesic or anesthetic; that the pharmacological agent is an antibiotic; that impelling the pharmacological agent comprises generating ultrasonic waves for impelling the pharmacological agent ultrasonically, impelling a plurality of pharmacological agents, impelling a first pharmacological agent using electrophoresis and impelling a second pharmacological agent using sonophoresis; or delivering a can into subcutaneous non-intrathoracic tissue of the patient, the can comprising an electrode or electrically conductive region, and a pharmacological agent and impelling using phoresis the pharmacological agent from at least a portion of the can to the subcutaneous non-intrathoracic tissue. Shapland et al. disclose an apparatus and method for delivering a drug or combination of drugs selectively and locally to an internal body tissue (see column 2, lines 22-25). The catheter includes a drug transport wall for engagement with a local area of the

passageway wall or tissue and a drug chamber for receiving a selected drug. The wall is constructed of at least perforated, permeable, or semi-permeable material through which the drug is to selectively pass (see column 2, lines 34-47 and 53-57). The catheter may be coated on its outer surface with hydrogel to improve contact with the vessel wall. The hydrogel may contain the drug to be delivered. The hydrogel may also be coated on the inside wall of a catheter for similar drug delivery (see column 8, lines 23-33). The drugs that are delivered by the device include antibiotics and sensitizers (see column 12, lines 53-58). Shapland et al. also disclose using phonophoresis, and that to perform phonophoresis, the catheter uses a piezoelectric transducer (see column 13, lines 3-52). Phonophoresis achieves greater penetration and more readily delivers an entire molecule (see column 13, lines 10-14). Transducers transfer one form of energy to another form of energy. Further, it would be obvious to combine the system and method taught by Kieval with the elements disclosed by Shapland et al. because providing drug delivery at the dissection area reduces pain and inflammation, providing therapy at a plurality of locations enables treatment of more than one target site, disposing the drug on the lead or impregnating the drug on a membrane on the lead enables the lead to treat more areas more readily, anesthetic provides temporary relief from pain, antibiotics treat abnormal health conditions, impelling a plurality of drugs can treat more than one condition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the system and method taught by Kieval with a transducer that provides sonophoresis; providing therapeutic treatment localized to a dissection path; that the pharmacological agent is

provided at a plurality of locations on the lead body; that the pharmacological agent is impregnated into a membrane provided on the lead; that the pharmacological agent is disposed on a coating on the lead; that the pharmacological agent is an analgesic or anesthetic; that the pharmacological agent is an antibiotic; that impelling the pharmacological agent comprises generating ultrasonic waves for impelling the pharmacological agent ultrasonically, impelling a plurality of pharmacological agents, impelling a first pharmacological agent using electrophoresis and impelling a second pharmacological agent using sonophoresis; or delivering a can into subcutaneous non-intrathoracic tissue of the patient, the can comprising an electrode or electrically conductive region, and a pharmacological agent and impelling using phoresis the pharmacological agent from at least a portion of the can to the subcutaneous non-intrathoracic tissue because phonophoresis achieves greater penetration and more readily delivers an entire molecule, transducers transfer one form of energy to another form of energy, providing drug delivery at the dissection area reduces pain and inflammation, providing therapy at a plurality of locations enables treatment of more than one target site, disposing the drug on the lead or impregnating the drug on a membrane on the lead enables the lead to treat more areas more readily, anesthetic provides temporary relief from pain, antibiotics treat abnormal health conditions, impelling a plurality of drugs can treat more than one condition.

Claims 20, 23-24, and 27-28 are rejected as being unpatentable over Kieval in view of Shapland et al. Kieval in view of Shapland et al. disclos the system and method described above but does not expressly disclose the can providing the sonophoresis,

that the pharmacological agent is impregnated into a membrane on the can, that the reservoir is coupled to a port on the can, or that the pharmacological agent covers at least 25% of the surface area of the can. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system and method for providing cardiac therapy as taught by Kieval in view of Shapland et al, with the can providing the sonophoresis, that the pharmacological agent is impregnated into a membrane on the can, that the reservoir is coupled to a port on the can, or that the pharmacological agent covers at least 25% of the surface area of the can, respectively, because Applicant has not disclosed that can providing the sonophoresis, that the pharmacological agent is impregnated into a membrane on the can, that the reservoir is coupled to a port on the can, or that the pharmacological agent covers at least 25% of the surface area of the can, respectively, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the lead providing sonophoresis, the pharmacological agent disposed on the lead, that the reservoir is coupled to the lead, that the agent covers a portion of the lead, respectively at taught by Kieval in view of Shapland et al, because it provides therapy to the target site, provides the drug to the area of discharge, and allows the lead to provide electrical stimulation, and since it appears to be an obvious matter of design choice to modify Kieval in view of Shapland et al. to obtain the invention as specified in the claims.

Claim 43 is rejected as being unpatentable over Kieval in view of Stokes (U.S. 4506680). Kieval discloses the system and method described above, but does not

disclose the sheath. Stokes does disclose the sheath (see column 2, lines 30-50). Inserting the lead through a sheath enables the lead to be inserting without damaging the lead. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was disclosed to combine the system and method disclosed by Kieval with the sheath in order to protect the lead during implantation.

Claims 59-62 are rejected as being unpatentable over Kieval in view of Schroeppel et al (U.S. 5749909). Kieval teaches the system and method described above, but does not teach providing a power signal to the device, a DC voltage, an AC voltage, or a DC bias voltage with an AC signal alternating at an ultrasonic frequency. Schroeppel et al. disclose the DC power signal and an AC voltage and a DC bias voltage with an AC signal alternating at an ultrasonic frequency (see column 2, lines 35-50 and column 8, lines 47-64). Providing the power in such a way enables efficient recharging of the battery without invasively replacing the power source. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the system and method disclosed by Kieval with the power signals disclosed by Schroeppel et al. in order to non-invasively replace power in the device.

Response to Arguments

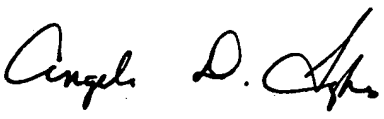
Applicant's arguments with respect to claims 1-66 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRS



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